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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

25225 7590 06/15/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-55 are pending* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 18, filed on 03//24/04. Claims 1-30 have been canceled. New claims 31-55 have been added. Claims 31-55 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 31-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavanchy et al. (J. Clinical Laboratory Analysis 1996, Vol. 10, pp. 269-276), Lee et al. (Trnasfusion 1995, Vol. 35, pp. 845-849), Rosa et al. (J. Virol. Methods 1995, Vol. 219, pp. 219-232) and Wang et al. (US patent No. 5,106,726A).

3. Claims invention is drawn to a diagnostic agent for hepatitis C virus (HCV) infection comprising a solid phase sensitized with a genetic recombinant HCV antigen and synthetic HCV antigens comprising core, NS4 and NS5 antigens. One scope of the invention is that the genetic recombinant HCV antigen is NS3. The solid phase can be directly sensitized with the genetic recombinant antigen. Both recombinant antigen and synthetic antigen can be conjugated with a carrier protein of BSA. The solid support can be a particle made by polystryrene latex particle or copolymer latex particle or erythrocyte or gelatin particle.

4. Lavachy et al. disclose several assays in which the detection agents comprising non-structural protein 3 (NS3), NS4, NS5 and structural protein core including the 3rd generations of

ELISA (Ortho HCV3.0) and RIBA (RIBA3.0), Wellcozyme WB, INNO-LLA and Cobas core anti-HCV EIA.. The diagnostic antigens comprising structural protein 3 (NS3), NS4, NS5 and structural protein core are all coated onto a solid supports (Table 3 on page 272). For the 3rd generations of ELISA (Ortho HCV3.0) and RIBA (RIBA3.0), Wellcozyme WB, INNO-LLA, the diagnostic antigens are coated onto a solid support, such as polysteryne 96 well plate or nitrocellular paper. For Cobas core assay, the detection agents of the NS3, NS5, NS4 and core are immobilized onto a polystyrene bead (See paper No. 270). They do not explicitly teach that the nonstructural protein of NS3, and core and NS4 are synthetic antigens. They also do not teach to use a synthetic NS5 peptide and conjugate the antigens with BSA.

5. Lee et al disclose that for the third generations of ELISA and RIBA, the c33c (NS3) and NS5 are recombinant antigens. The C100 (NS4) and c22 (core) are synthetic peptide antigens (See page 846).

6. Rosa et al. teach to use a short synthetic NS5 peptide antigen instead of a genetic recombinant NS5 to do the ELISA assay. Rosa et al. disclose to link the synthetic NS 5 antigenic peptides with synthetic NS4 antigen (NS4-GG-NS5). By using this synthetic antigen peptide alone with the recombinant NS3 and core antigens in an ELISA assay, they found that the results was 100% for all panels (See section of 3.5 on page 229) that agreed with the results to Ortho or Abbot second generation assays. They further point out that certain recombinant NS5 polypeptide used in some current assays produce non-specific false positive results. The use of short synthetic peptides disclose by their publication should be helpful in excluding amino acid sequences that may be responsible for the low specificity due to cross-reactivity with antibodies directed against other viral proteins (See page 230). They did not teach explicitly to conjugate the BSA to the peptide antigen.

7. Wang C. teach a method of conjugating HCV peptide antigen with BSA and coating the erythrocyte or some solid particle with the conjugated antigen. They conclude that this conjugated antigen is good for both quantitative and qualitative detection of antibodies to HCV in specimens including serum and biofluid (See cols. 35 & 36).

8. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to use the detecting agent comprising a recombinant antigen NS3 and synthetic antigens NS4, NS5 and core as taught by

Lavachy et al. and Rosa et al., and then conjugate the peptide antigens with BSA and use them to coat the solid particle as taught by Wang C. et al. absence of unexpected results. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

June 1, 2004

James C. Housel 6/11/04
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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